

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICATION NUMBER: **10/568,488**
FILING DATE: **02/14/2006**
FIRST NAMED INVENTOR: **Brett P. Monia**
ART UNIT: **1635**
EXAMINER NAME: **To Be Determined**
ATTORNEY DOCKET NUMBER: **ISPH-0859USA**
TITLE: **ANTISENSE MODULATION OF P38
MITOGEN ACTIVATED PROTEIN
KINASE EXPRESSION**

MAIL STOP AMENDMENT
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P.O. BOX 1450
ALEXANDRIA, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Under 37 C.F.R. §§ 1.56 and 1.97-98

SIR:

Pursuant to the provisions of 37 C.F. R. §§ 1.56 and 1.97-98, enclosed herewith is PTO Form PTO/SB/08A listing references for consideration by the Examiner.

The filing of this Information Disclosure Statement shall not be construed as a representation regarding the completeness of the list of references, or that inclusion of a reference in this list is an admission that it is prior art or is pertinent to this application, or that a search has been made, or as an admission that the information listed is, or may be considered to be, material to patentability, or that no other material information exists, and shall not be construed as an admission against interest in any manner.

This Information Disclosure Statement is being filed:

☒ within three months of the filing date of the application, or date of entry into the national stage of an international application, or before the mailing date of a first office action on the merits, whichever event last occurred;

- ☐ before the mailing of a first official action after filing of a request for continued examination (RCE) under 37 C.F.R. § 1.114;
- ☐ after three months of the filing date of this national application or the date of entry of the national stage in an international application, or after the mailing date of the first official action on the merits, whichever event last occurred, but before that mailing date of the first office action to occur of either: (1) a final action under 37 C.F.R. § 1.113; or (2) an action that otherwise closes prosecution in the application, and:

☐ attached hereto is the fee set forth under 37 C.F.R. § 1.17(p) for submission of this Information Disclosure Statement under 37 C.F.R. § 1.97(c); OR

☐ Applicant certifies pursuant to 37 C.F.R. § 1.97(e) that:

☐ each item of the information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Statement;

OR

☐ no item of information contained in this Information Disclosure Statement was cited in a counterpart foreign application and, to the knowledge of the person signing this certification after making reasonable inquiry, no item of information contained in this Statement was known to any individual designated under 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Statement.

- ☐ on or before the payment of the issue fee but after the mailing date of the first to occur of either: (1) a final action under 37 C.F.R. § 1.113; (2) a notice of allowance under 37 C.F.R. § 1.311; or (3) an action that otherwise closes prosecution in the application, and:

☐ Applicant certifies pursuant to 37 C.F.R. § 1.97(e) that:

☐ each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign

patent office in a counterpart foreign application not more than three months prior to the filing of this statement;

OR

☐ no item of information contained in this Information Disclosure Statement was cited in a counterpart foreign application and, to the knowledge of the person signing this certification after making reasonable inquiry, no item of information contained in this Statement was known to any individual designated under 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Statement. AND

☐ attached hereto is the fee set forth under 37 C.F.R. § 1.17(p) for submission of this Information Disclosure Statement under 37 C.F.R. § 1.97(c); OR

☐ after the payment of the issue fee. Applicant requests that the information contained in this Information Disclosure Statement be placed in the file according to 37 C.F.R. § 1.97(i), although the information may not be considered by the USPTO.

☒ Enclosed is a copy of each listed reference that may be material to the examination of this application, and for which there may be a duty to disclose.

☒ This application relies, under 35 U.S.C. § 120, on the earlier filing date of prior application No. 10/641,455, filed on 08/15/2003, and the references cited therein are hereby referenced, but are not required to be provided in this application under 37 C.F.R. § 1.98(d).

☒ This application was filed after June 30, 2003. Therefore, pursuant to the waiver of the requirements under 37 C.F.R. § 1.98(a)(2)(i), copies of each U.S. Patent and each U.S. Patent Application Publication are not required to be submitted. Copies of any foreign patent documents and non-patent literature cited herein are enclosed.

☐ Each item of information contained in this Information Disclosure Statement was cited in the communication from a foreign patent office in a counterpart application, and the communication was not received by any individual designated in 37 C.F.R. § 1.56(c)

more than thirty days prior to the filing of this Information Disclosure Statement 37
C.F.R. § 1.704(d).

☒ Applicant submits that no fee is required for the consideration of this Information
Disclosure Statement. However, if a fee is due, the Commissioner is hereby authorized
to charge Deposit Account No 500252 referencing case number ISPH-0859USA.
Consideration of the listed references and favorable action are solicited.

Respectfully Submitted,



Colleen J. McKiernan
Registration No.: 48,570
Isis Pharmaceuticals, Inc.
1896 Rutherford Road
Carlsbad, CA 92008

Dated: July 18, 2006

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Not for submission under 37 CFR 1.99)

Application Number	10568488
Filing Date	2006-02-14
First Named Inventor	Monia
Art Unit	1635
Examiner Name	To Be Determined
Attorney Docket Number	ISPH-0859USA

U.S. PATENTS

Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1	5801154		1998-09-01	Baracchini et al.	
	2	6140124		2000-10-31	Monia et al.	
	3	6448079		2002-09-10	Monia et al.	

If you wish to add additional U.S. Patent citation information please click the Add button.

U.S. PATENT APPLICATION PUBLICATIONS

Examiner Initial*	Cite No	Publication Number	Kind Code ¹	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1	20030176383	A1	2003-09-18	Monia et al.	
	2	20040171566	A1	2004-09-02	Monia et al.	

If you wish to add additional U.S. Published Application citation information please click the Add button.

FOREIGN PATENT DOCUMENTS

Examiner Initial*	Cite No	Foreign Document Number ³	Country Code ²	Kind Code ⁴	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	T ⁵
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1	9835978	WO	A1	1998-08-20	Isis Pharmaceuticals		<input type="checkbox"/>
2	9960166	WO	A1	1999-11-25	Isis Pharmaceuticals		<input type="checkbox"/>

If you wish to add additional Foreign Patent Document citation information please click the Add button

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁵
	1	AGRAWAL, S. et al., "Antisense therapeutics: is it as simple as complementary base recognition?" Molecular Medicine Today (2000) 6:72-81.	<input type="checkbox"/>
	2	AOSHIBA, K. et al., "Role of p38-Mitogen-Activated Protein Kinase in Spontaneous Apoptosis of Human Neutrophils," J. Immunol. (1999) 162:1692-1700.	<input type="checkbox"/>
	3	ARIMA, H. et al., "Specific Inhibition of Nitric Oxide Production in Macrophages by Phosphorothioate Antisense Oligonucleotides," J. Pharm. Sci. (1997) 86(10):1079-1084.	<input type="checkbox"/>
	4	BRANCH, A. D., "A good antisense molecule is hard to find," TIBS (1998) 23:45-50.	<input type="checkbox"/>
	5	CHIALDA, L. et al., "Inhibitors of mitogen-activated protein kinases differentially regulate costimulated T cell cytokine production and mouse airway eosinophilia," Respiratory Research (2005) 6:36.	<input type="checkbox"/>
	6	COHEN, P. S. et al., "The Critical Role of p38 MAP Kinase in T Cell HIV-1 Replication," Molecular Medicine (1997) 3 (5):339-346.	<input type="checkbox"/>
	7	CROOKE, S. T., "Basic Principles of Antisense Therapeutics," Antisense Research and Application (1998) Springer-Verlag, New York, pp. 1-50.	<input type="checkbox"/>

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Attorney Docket Number	ISPH-0859USA

8	DATABASE EMBL:HS1206359 "zv25e08.s1 Soares_NhHMPu_S1 Homo sapiens cDNA clone IMAG:754790 3' similar to TR:G1304132 G1304132 TPRD.; mRNA sequence," 4 May 1997 XP002302626 retrieved from EBI accession no. EM_EST:1206359 Database accession no. HS1206359.	<input type="checkbox"/>
9	DUAN, W. et al., "Inhaled p38 Mitogen-Activated Protein Kinase Antisense Oligonucleotides Attenuates Asthma in Mice," Am. J. Respir. Crit. Care Med. (2005) 171:571-578.	<input type="checkbox"/>
10	GREEN, D. W. et al., "Antisense Oligonucleotides: An Evolving Technology for the Modulation of Gene Expression in Human Disease," J. Am. Coll. Surg. (2000) 191:93-105.	<input type="checkbox"/>
11	HAN, J. et al., "A MAP Kinase Targeted by Endotoxin and Hyperosmolarity in Mammalian Cells," Science (1994) 265:808-811.	<input type="checkbox"/>
12	JEN, K.-Y. et al., "Suppression of Gene Expression by Targeted Disruption of Messenger RNA: Available Options and Current Strategies," Stem Cells (2000) 18:307-319.	<input type="checkbox"/>
13	KUMAR, R. K. et al., "Murine Model of Chronic Human Asthma," Immunology and Cell Biology (2001) 79:141-144.	<input type="checkbox"/>
14	NAGATA, Y. et al., "Activation of p38 MAP Kinase and JNK But Not ERK Is Required for Erythropoietin-Induced Erythroid Differentiation," Blood (1998) 92(6):1859-1869.	<input type="checkbox"/>
15	NICK, J. A. et al., "Role of p38 Mitogen-Activated Protein Kinase in a Murine Model of Pulmonary Inflammation," J. Immunol. (2000) 164:2151-2159.	<input type="checkbox"/>
16	NYCE, J. W., "Respirable antisense oligonucleotides as novel therapeutic agents for asthma and other pulmonary diseases," Expert. Opin. Investig. Drugs (1997) 6(9):1149-1156.	<input type="checkbox"/>
17	NYCE, J. W. et al., "DNA antisense therapy for asthma in an animal model," Nature (1997) 385(6618):721-725.	<input type="checkbox"/>
18	RICHARDS, I. M., "Mouse models of allergic disease; how do they relate to asthma in man?" Clinical and Experimental Allergy (1998) 26:618-620.	<input type="checkbox"/>

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Application Number	10568488
Filing Date	2006-02-14
First Named Inventor	Monia
Art Unit	1635
Examiner Name	To Be Determined
Attorney Docket Number	ISPH-0659USA

19	SALE, E. M. et al., "Use of an antisense strategy to dissect the role of MAP kinases in cellular signaling," Biochemical Society Transactions (1998) 26(3):S254.	<input type="checkbox"/>
20	TEMELKOVSKI, J. et al., "An improved murine model of asthma selective airway inflammation, epithelial lesions and increased methacholine responsiveness following chronic exposure to aerosolised allergen," Thorax (1998) 53:849-856.	<input type="checkbox"/>
21	WONG, W. S. F., "Inhibitors of the tyrosine kinase signaling cascade for asthma," Current Opinion in Pharmacology (2005) 5:264-271.	<input type="checkbox"/>

If you wish to add additional non-patent literature document citation information please click the Add button

EXAMINER SIGNATURE

Examiner Signature	Date Considered
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST 3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	10588488
Filing Date	2006-02-14
First Named Inventor	Monia
Art Unit	1635
Examiner Name	To Be Determined
Attorney Docket Number	ISP0859USA

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).


☐ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ None

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature		Date (YYYY-MM-DD)	2006-07-18
Name/Print	Colleen J. McKiernan	Registration Number	48,570

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**